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SECTION 12: 510(k) SUMMARY

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ODi
ORTHOPEDIC
DESIGNS, INC.

Premarket Notification

510(k) Summary of Safety and Effectiveness Information

For Release Upon Request Only

Date of Preparation: February 17, 2003

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: Orthopedic Designs, Inc. (ODi)
6965 1st Ave. North
St. Petersburg, FL 33710

Contact: Patrick Cosgrove
(888) 635-8535

Establishment Registration Number: 1064129

Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener –and- Single/multiple Component Metallic Bone Fixation Appliances and Accessories.

Classification Reference: 21 CFR § 888.3040 – Smooth or Threaded Metallic Bone Fixation Fastener

21 CFR § 888.3030 – Single/multiple Component Metallic Bone Fixation Appliances and Accessories.

Common Used Name: Cannulated Screw

Device Product Code: HWC and HTN

Classification Panel: 87- Orthopedic Devices

Trade Proprietary Name: ODi 7.0mm Cannulated Screw System

Proposed Regulatory Class: Class II

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Device Description:

The ODi 7.0mm Cannulated Screw System is used for fixation and stabilization of fractures of the proximal and distal femur until bony union can occur. The system consists of the following parts:

- Cannulated screws of various lengths, which are positioned through bony fragments to provide stability to the fracture site during healing.
- A washer which provides a bearing surface for the cannulated screw head against the bone. The washer also prohibits migration of the screw head into the cortex.

ODi will manufacture the implants from implant grade titanium alloys.

Indications for Use:

The ODi 7.0mm Cannulated Screw System will be used on indications that are common with presently marketed cannulated screw systems. The primary indications are for fixation/stabilization of stable fractures of the proximal femur including pertrochanteric fractures, basilar femoral neck fractures, subcapital femoral fractures, and combinations of these fractures. Other indications include intercondylar femoral fractures and tibial plateau fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

Contra-indications for Use:

The ODi 7.0mm Cannulated Screw System is not intended for use in patients with the following conditions:

1. Active local Infection.
2. Metal sensitivity or allergic reaction to foreign bodies.
3. Loss of bone stock or insufficient bone quality to support the device.
4. Obliterated femoral head, neck or trochanteric region.
5. Use in the spine

Substantial Equivalent Devices:

Orthopedic Designs, Inc. believes the ODi 7.0mm Cannulated Screw System is substantially equivalent to the products described herein with respect to indications for use, device design, materials, method of manufacture and method of sterilization. Within the proposed class, the following devices are used as predicate devices for comparison:

aaP Implants, Inc	K990776
Alphatec Mfg., Inc	-NA-
Advanced Orthopaedic Solutions	K014185
DePuy/ACE, Inc.	K893512
Magly Orthopedics, LLC	K021662
Smith and Nephew	-NA-
Stryker,Inc.-HowmedicaOsteonics	-NA-
Synthes, Inc.	K021932 K962011

Each of these products are commercially available and marketed Class II devices indicated for similar use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

Mr. Patrick J. Cosgrove
Vice President Engineering and Product Support
Orthopedic Designs, Inc.
6965 1st Avenue North
St. Petersburg, FL 33710

Re: K030619
Trade/Device Name: ODi 7.0mm Cannulated Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: February 24, 2003
Received: February 27, 2003

Dear Mr. Cosgrove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

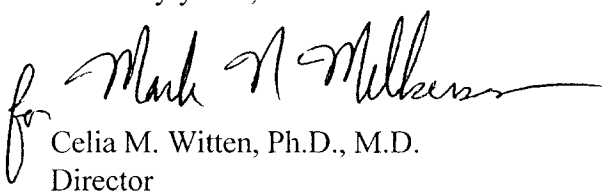
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5: DEVICE INDICATIONS FOR USE

510(k) Number:

Device Name: ODi 7.0mm Cannulated Screw System

Indications For Use:

The ODi 7.0mm Cannulated Screw System will be used on indications that are common with presently marketed cannulated screw systems. The primary indications are for fixation/stabilization of stable fractures of the proximal femur including pertrochanteric fractures, basilar femoral neck fractures, subcapital femoral fractures, and combinations of these fractures. Other indications include intercondylar femoral fractures and tibial plateau fractures. The device is intended to stabilize fragments of the fracture until bony union can occur.

Contra-Indications:

The ODi 7.0mm Cannulated Screw System is not intended for use in patients with the following conditions:

1. Active local Infection.
2. Metal sensitivity or allergic reaction to foreign bodies.
3. Loss of bone stock or insufficient bone quality to support the device.
4. Obliterated femoral head, neck or trochanteric region.
5. Use in the spine

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(per 21 CFR 801.109)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030619